



Re Patent Application of:
FABIAN HAISCHMANN et al.
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Remarks

New Claims 2-23 have been presented. No new matter has been incorporated thereby.

Conclusions

If the prosecution of the application can be facilitated through telephone interview between the Examiner and the undersigned, the Examiner is requested to telephone the undersigned at the Examiner's convenience.

Respectfully submitted,

Jacqueline E. Hartt, Ph.D.
Reg. No. 37,845
ALLEN, DYER, DOPPELT, MILBRATH & GILCHRIST, P.A.
255 South Orange Avenue, Suite 1401
P.O. Box 3791
Orlando, Florida 32802
(407) 841-2330
Agent for Applicant

CERTIFICATE OF MAILING

I hereby certify that the foregoing is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, this **18th** day of February, 2004.

Edward Bradley

DEVICE FOR RINSING A BODY CAVITY

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to German application DE 102 33
5 053.0-35, filed July 19, 2002, the contents of which are incorporated
hereinto by reference.

FIELD OF THE INVENTION

The invention relates to a device and method for rinsing a body cavity with a
10 fluid, and specifically for controlling a fluid flow therefor.

BACKGROUND OF THE INVENTION

Devices for rinsing a body cavity are known in the art wherein change-over of a
suction line to preset values is performed by signal contacts of an operating unit for a
15 medical instrument such as a shaver and application of this signal for controlling a
suction/rinse device. Simultaneously, a change-over of the suction line between shaver
and drainage cannula takes place.

A disadvantage of such a device is that, when a shaver is used, the operating
conditions "on" and "off" are transmitted to the system by the signal contacts, typically a
20 foot switch. In the simplest case, this may take place by signal lines having plug
connections. This is expensive, in particular in construction. Furthermore, there are
functional sources of faults, for instance, due to bad contacts by contact corrosion and

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the like. Finally, the plug connections are subject, due to frequent operation, to wear. A particularly important drawback is that the shaver must be compatible with the device, since a signal exclusively comprises the digital information "on" and "off", and consequently the control system in a control unit must be set for a second medical instrument to be employed, for instance, the shaver. If such a setting is not possible, a specific medical instrument only may be operated by the control unit. As a result, there is no compatibility between a single control unit and several different medical instruments and/or identical medical instruments of different manufacturers and different specifications with regard to the flow resistance.

Finally, it is believed disadvantageous in prior known devices that with the signaling of the operating condition from "off" to "on" of the second medical instrument on the feed side of the body cavity, an immediate increase of the flow takes place, while the increased discharge of fluid through the second medical instrument is comparatively slow. Thus a risk of a potentially medically dangerous pressure peak in the body cavity is present.

SUMMARY OF THE INVENTION

The present invention is therefore directed to providing a device, method of use, and method of making, for rinsing a body cavity with a fluid by means of which controlled flow and pressure meeting predetermined requirements is obtained, without the necessity of signal lines and independent of a second medical instrument being employed.

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The device of the present invention for rinsing a body cavity with a fluid comprises a rinse pump for introducing fluid into a body cavity and a pressure sensor on a pressure side of the rinse pump. Means are provided for inserting a medical instrument into the body cavity, the medical instrument comprising means for establishing fluid communication with the body cavity. A suction pump is in fluid communication along a first pathway with the establishing means and along a second pathway with the body cavity. Means are provided for controlling fluid flow along the second pathway. A control unit is in signal communication with the rinse pump, the pressure sensor, the suction pump, and the flow controlling means. The control unit is for receiving pressure values from the pressure sensor and for controlling the rinse pump, the suction pump, and the flow controlling means in response to the received pressure values. The control unit is thus operative to control fluid flow through the body cavity depending on an operating condition of the medical instrument.

In the following, preferred embodiments of the invention are explained in more detail, with figures representing exemplary embodiments only.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 a schematic view of the device of the present invention.

FIG. 2 a detailed schematic view of a means for varying flow resistance.

FIG. 3 illustrates the hose set used according to the invention, the inset illustrating the configuration thereof.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In FIG. 1 can be seen a device for rinsing a body cavity 1 with a fluid. This device is provided with a storage container 2 for the fluid and with a controllable rinse pump 3 connected to the storage container 2. A supply line 4 is connected to the pressure side of the rinse pump 3. The supply line 4 is provided with a first medical instrument comprising a rinse channel 5, said first medical instrument being insertable into the body cavity 1. On the pressure side of the rinse pump 3 a pressure sensor 6 is provided for the determination of the actual pressure.

This embodiment is equipped with a drainage cannula 7 in fluid communication with a drainage line 8 insertable into the body cavity 1, and with a second medical instrument 9 insertable into the body cavity 1 and comprising a suction line 10, a controllable volume flow through the body cavity being "high" or "low", depending on the operating condition "on" or "off" of the second medical instrument 9. The drainage cannula 7 and the suction line 10 are connected to a suction pump 11. Flow through the drainage line 8 is provided with controlled using a flow resistance controller 12. The rinse pump 3, the pressure sensor 6, and the flow resistance controller 12 are in signal communication with a control unit 13.

In FIG. 2 is illustrated a preferred embodiment of the flow resistance controller 12, comprising a hose clamping device comprising a hose 14, the hose wall 15 comprising an elastic material. The hose clamping device has a support 16 upon which the hose 14 rests, the support 16 having a wall 161, and a pressure piece 17. The pressure piece 17 is substantially perpendicular to the support wall 161, so that

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pressure in the direction of the support wall 161 can be exerted on the hose wall 15.

The pressure piece 17 is connected by a spindle gearing 18 with an electro-motor drive 19.

In the following, the mode of operation of the invention is explained in more
5 detail. The suction pump 11 operates with a suction capacity being equivalent, when a
shaver 9 is used, to the corresponding flow in the operating condition "on" of the shaver
9, and is reduced in the operating condition "off" by the control system 13 by
proportionally and continuously adjustable hose clamping 12 to the desired drainage
capacity. In the operating condition "on" is formed a by-pass over the shaver 9,
10 arranged parallel to the drainage line 8. The internal body cavity pressure is reduced
due to the addition of the two volume flows through drainage line 8 and suction line 10.
This pressure drop is very quickly recorded by the pressure sensor 6. The control unit
[[11]] 13 connected to the pressure sensor 6 detects the drop and thus detects the
operating condition "on" of the shaver 9 and sends a control signal to the hose clamping
15 device 12 to clamp the drainage line 8. Simultaneously, the rinse pump 3 is adjusted to
[[an]] increase [[of]] the pump capacity to a pre-selected value. By control of the suction
pump 11, a pressure adjustment is made by variation of the pump capacity, depending
on the pre-selected pressure. This pressure may in principle and independent of this
specific embodiment comprise different pre-selected values for the operating conditions
20 of a second medical instrument 9. When the shaver 9 is switched off, the internal body
cavity pressure will temporarily rise, lacking discharge flow through the suction line 10.
An increase of the pressure above the pre-selected internal pressure is also recorded

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by the pressure sensor 6; the reverse processes take place, as described above. In the operating condition "off" of the shaver 9, the pressure can be adjusted by the pump capacity of the rinse pump 3, the pump capacity of the suction pump 11 and/or the hose clamping device 12.

5 Independent of the above embodiment, a determination of the actual internal pressure in the body cavity 1 may be performed by stopping the rinse pump 3 and the suction pump 11, the measured value received from the pressure sensor 6 corresponding to the actual internal pressure, owing to the static conditions (flow is virtually zero). These steps can be performed alternately with the operating condition
10 described above. Furthermore, it is possible that differences in the measured values of the pressure sensor 6 can be used in the employed intervals (flow = pre-set, flow = 0) for an internal calibration and adjustment to the first medical instrument 5 or the pressure drop thereacross. Then the control unit 13 will take these differences into account for the adjustment described above to a pre-set desired pressure value, i.e., to
15 a relatively correspondingly higher measured value of the pressure sensor 6. This may, if applicable, also take place in a calibration curve determined after connection of a specific first medical instrument 5, so to speak "learned", and stored in the control unit 13. It is recommended that "learning" be performed after connecting a first medical instrument and prior to or at the beginning of a treatment.

20 FIG. 3 illustrates a hose set for a device according to the invention, comprising a T piece 20 and hoses 21, 22, 23 connected to said T piece 20, wherein a first hose 21 is intended for the connection to [[a]] the second medical instrument 9, a second hose 22

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forms at least part of the drainage line 8, and a third hose 23 is intended for the connection to the suction pump 11. As an option the first hose 21 and the third hose 23 are made from a polymer having a hardness of at least shore A 70, preferably 75, and the second hose 22 is made from a polymer having a hardness of less than shore A 70, preferably 65. The T piece 20 is made from an inherently stable plastic material and is adapted in a positive locking manner complementarily to a T piece positive locking cutout 24 provided as one unit together with a flow resistance controller 12. This unit is, if applicable, releasably attached to a device wall in turn supporting the drive means 19 for the pressure piece 17, by which the pressure piece 17 is drivable against the support wall 161 and thus clamps the second hose 22 down. It is understood that the second hose 22 preferably has, at least in the area between the pressure piece 17 and the support wall 161, the aforementioned lower shore hardness. Insertion of the T piece 20 into the T piece positive locking cutout 24 and fixation therein immediately follow from examination of FIG. 3.

In an alternative method of operation of a device according to the invention, the suction pump 11 operates with an adjustable suction capacity (flow, speed) predetermined to a value appropriate for the second medical instrument, e.g., shaver 9, but not dependent on the actual pressure in the internal body cavity 1. The suction pump 11 is, instead, continuously operated by the control unit 13 at a speed that corresponds to the desired flow through the second medical instrument 9 when activated. Accordingly, a reduced pressure is created in the hoses [[8,9]] 8,10 between the suction pump 11, second medical instrument 9, and the flow resistance controller

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12. When the second medical instrument 9 is activated, the flow through the second medical instrument 9 rises from a minimum value or from zero to an operating level, wherein the operating flow depends on the suction pump 11 speed adjustment selected by an operator or predetermined otherwise, e.g., by programming of the control unit 13.

5 The increased flow through the second medical instrument 9 (wherein the position of the flow resistance controller 12 remains the same at least initially) leads to a pressure drop in the body cavity 1. Upon detection of this pressure drop by the pressure sensor 6, the control unit 13 increases the flow through the rinse pump 11, e.g., the speed thereof, in order to compensate for the pressure drop. If this increased rinse pump 11
10 flow does not achieve full compensation for the pressure drop (i.e., recovery of the pressure in the body cavity 1 before activation of the second medical instrument 9), the control unit 13 further controls the flow resistance controller 12 to increase the flow resistance and thus to reduce the total flow from the body cavity ~~[[1to]]~~ 1 to the suction pump 11. The latter feature comprises operating the flow resistance controller 12 below
15 maximum flow resistance when the second medical instrument 9 is not activated.

The present invention provides that a decrease of the actual pressure measured by the pressure sensor 6 from a given required pressure can be detected, when the second medical instrument is changed ~~[[over]]~~ from "off" to "on", providing for the issuance of a control signal for the flow resistance controller 12, the rinse pump 3,
20 and/or the suction pump 11, and that according to a pre-set required feed capacity of the rinse pump and/or of the suction pump for the operating condition "on" and to the required pressure, and vice versa.

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In other words, in for instance the operating condition "off" of a shaver 9, suction of the fluid from the body cavity 1 essentially takes place through the drainage line 8. By changing the shaver ~~ever into~~ 9 to operating condition "on", so to speak a by-pass, the suction line 10 to the drainage line 8 is activated, with the consequence of a (temporary) pressure drop in the body cavity. This pressure drop is detected, with the consequence that the flow is increased by the control action of the rinse pump 3 to a pre-selected value (higher than for shaver "off"). The pressure control may then with constant flow take place by means of control of the suction pump 11.

The present invention achieves that the flow and the pressure in the body cavity 1 can freely and independently ~~[[from]]~~ of each other be controlled and held constant, irrespective of the operating condition of the second medical instrument 9. Control of the flow is more rapidly performed with this invention for ~~[[the]]~~ a variation of ~~[[the]]~~ flow resistance than with a speed-controlled roller pump, due to the smaller weights and moments of inertia of the flow resistance controller 12. The adaptation of the flow and, if necessary, the setting and re-adjustment of the pressure takes place according to the operating condition "on" or "off" of the second medical instrument 9. It is also advantageous that pressure variations in the body cavity 1 are detected by the system in a very short time and can be corrected to the desired pressure value, so that the pressure in the body cavity 1 is also held virtually constant, when the operating conditions of the second medical instrument 9 are changed. Another advantage is that ~~every~~ any medical instrument can be used, without expensive adaptations of signal lines and plug connections, since control and regulation mechanisms provide in every case for

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setting and holding the pre-set values ~~[[for]]~~ of pressure and flow constant. Finally, the arrangement of the flow resistance controller 12 in conjunction with the drainage line 8 is advantageous, since the pressure and flow regulation follow the switching on of the medical instrument, thus avoiding pressure peaks that can potentially represent health risks. Simultaneously, any leakages due to the delay of the regulation are automatically and without additional measures detected. Finally, a virtually constant body cavity extension distension and correspondingly ~~a good view by~~ with an endoscopic optical system can be achieved.

The first medical instrument 5 may be selected from ~~[[the]]~~ a group including a rinse probe, rinse cannula, trocar with optical system, and optical system with rinse channel, although these are not intended as limitations.

The rinse pump 3 may comprise a drive unit having a motor with a rotating driven shaft and a pump unit (mechanically, i.e., by self substance, positive locking, or force locking, or magnetically, i.e., by force locking) connected to the drive shaft and rotationally driven, the feed capacity being controllable by varying the speed of the motor. In particular, this may be a peristaltic pump. Alternatively, the rinse pump 3 may comprise an elastic storage container with a controllable pressure cuff fully or partially surrounding the storage container, the feed capacity being controllable by regulation of the pressure cuff. Finally, the rinse pump 3 may further comprise a height level-variable storage container, the feed capacity being controllable by regulation of the height level of the storage container.

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The second medical instrument 9 may be selected from ~~[[the]]~~ a group including a shaver, sampling device, and suction probe, although these are not intended as limitations. In particular in the case of a shaver, it is recommended that in the operating condition "on", the volume flow through the second medical instrument 9 be "high" and
5 vice versa. However, the ~~reversed~~ opposite relation may also be possible.

In principle, the control unit and the components connected thereto may be operated or controlled hydraulically, pneumatically, or electrically, with electrical or electro-mechanical operation being preferred.

The flow resistance controller 12 may be controllable proportionally, continuously,
10 or in a multitude of discrete steps. It is preferred that the flow resistance controller comprise a hose clamping device with a hose as discussed above. The hose walls preferable comprise an elastic material. In detail, the flow resistance controller 12 may comprise a support surface upon which the hose wall rests, and may be provided with a pressure piece, by means of which pressure in the direction of the support surface is
15 exerted on the hose wall. It is preferred that the pressure piece be linearly drivable and connected by a spindle gearing to an electro-motor drive, preferably a stepping motor. Depending on the control and regulation characteristic, nonlinear functions between a control signal and the movement of the pressure piece may, however, also be provided. An example for this is a rotating, linearly driven round eccentric disk the surface of
20 which runs against the hose wall or a pressure piece. By means of a cam, any desired kinematics may be achieved.

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It is recommended that the drainage line 8 and the suction line 10 or the suction pump 11, respectively, terminate in a collection vessel 25.

The invention further teaches a method for the operation of a device according to the invention, wherein at change-over of a second medical instrument 9 between two
5 operating conditions correlated with different flows in the suction line 10, by means of a pressure sensor 6 and the control unit 13 a pressure variation can be detected. ~~[[, by]]~~
By means of the control unit 13, upon detection of a pressure variation, the flow resistance controller ~~[[are]]~~ is activated according to an adjustment to a given desired flow and/or pressure associated with the active operating condition of the second
10 medical instrument 9. With regard to adjustment processes, it is recommended that upon a detection of a pressure variation, additionally the rinse pump 3 and/or the suction pump 11 are activated by the control unit 13 according to the adjustment to a given desired flow and/or pressure associated with the active operating condition of the second medical instrument 9.

15 Such devices may be, for instance, employed for endoscopic examinations and distension or resection of tissues, in particular under endoscopic control. A body cavity may be a cavity of a joint, for instance, a knee or a shoulder joint, a cavity between muscles or organs, or an organ itself forming or comprising a cavity. A fluid is in particular a liquid. This may be a homogeneous liquid phase or also a dispersion or an
20 emulsion. A drainage cannula may perform, in addition to the drainage function, further functions, as for instance an illumination of the body cavity by a light source integrated in the drainage cannula. Different volume flows with different operating positions are

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differentiated, in the meaning of the invention, by the terms "high" and "low", the absolute values being irrelevant. These terms serve for nothing more than indicating how the volume flows are relative to each other in the respective operating conditions of the second medical instrument.

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What is claimed is:

1. A device for rinsing a body cavity with a fluid comprising:
 - a rinse pump for introducing fluid into a body cavity;
 - a pressure sensor on a pressure side of the rinse pump;
 - 5 means for inserting a medical instrument into the body cavity, the medical instrument comprising means for establishing fluid communication with the body cavity;
 - a suction pump in fluid communication along a first pathway with the establishing means and along a second pathway with the body cavity;
 - means for controlling fluid flow along the second pathway; and
 - 10 a control unit in signal communication with the rinse pump, the pressure sensor, the suction pump, and the flow controlling means, for receiving pressure values from the pressure sensor and for controlling the rinse pump, the suction pump, and the flow controlling means in response to the received pressure values, operative to control fluid flow through the body cavity depending on an operating condition of the medical
 - 15 instrument.

ABSTRACT

A device for rinsing a body cavity with a fluid includes a rinse pump for introducing fluid into a body cavity and a pressure sensor on a pressure side of the rinse pump. A medical instrument insertable into the body cavity is adapted to establish fluid communication with the body cavity. A suction pump is in fluid communication along a first pathway with the medical instrument and along a second pathway with the body cavity. Fluid flow along the second pathway is controllable. A control unit receives pressure values from the pressure sensor, controls the rinse pump, the suction pump, and the flow controller in response to received pressure values, and is thus operative to control fluid flow through the body cavity depending on an operating condition of the medical instrument.